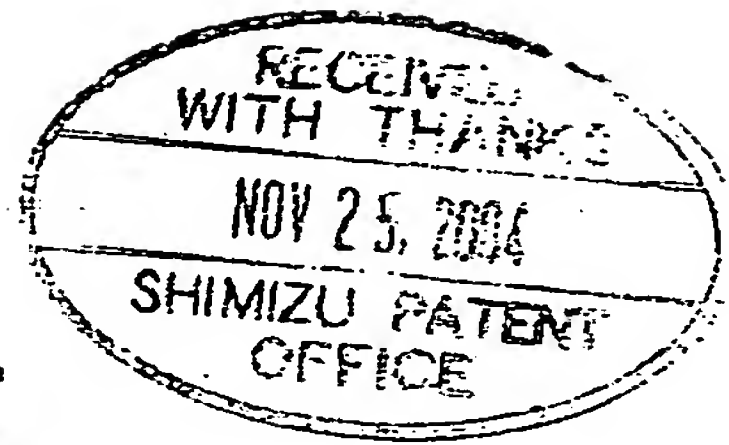


# PATENT COOPERATION TREATY



From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

## PCT

To:

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Tsuchiura-shi, Ibaraki 300-0847  
JAPON

WRITTEN OPINION

(PCT Rule 66)

Date of mailing (day/month/year) <span style="float: right;">22/11/2004</span>	
Applicant's or agent's file reference <span style="float: right;">RCJ-A0214P</span>	<b>REPLY DUE</b> within 2 / 00 months/days from the above date of mailing
International application No. <span style="float: right;">PCT/JP03/04458</span>	International filing date (day/month/year) <span style="float: right;">08/04/2003</span>
Priority date (day/month/year) <span style="float: right;">08/04/2003</span>	
International Patent Classification (IPC) or both national classification and IPC <span style="float: right;">C12Q1/68</span>	
Applicant <span style="float: right;">F. HOFFMANN-LA ROCHE AG et al.</span>	

1. This written opinion is the first drawn up by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
  - I ☒ Basis of the opinion
  - II ☐ Priority
  - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☐ Lack of unity of invention
  - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application
3. The applicant is hereby invited to reply to this opinion.
 

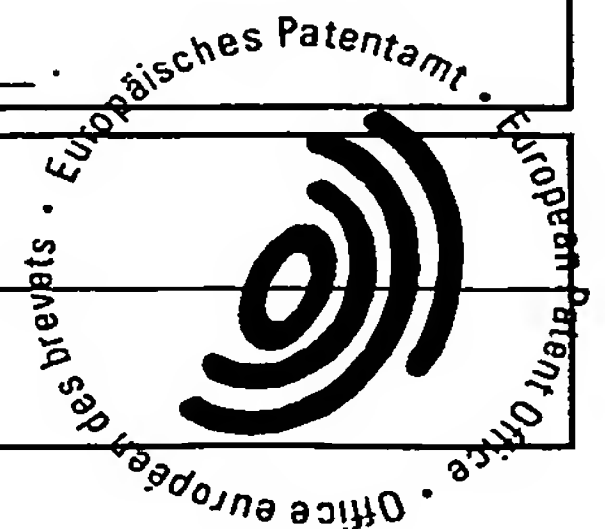
**When?** See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also** For an additional opportunity to submit amendments, see Rule 66.4.  
 For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis.  
 For an informal communication with the examiner, see Rule 66.6.

**If no reply is filed,** the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 08/08/2005

Name and mailing address of the IPEA/  European Patent Office D-80298 Munich Tel. (+49-89) 2399-0, Tx: 523656 epmu d Fax: (+49-89) 2399-4465	Authorized officer Examiner  Formalities officer (incl. extension of time limits) Tel. (+49-89) 2399 2828
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**WRITTEN OPINION**

International application No.

PCT/JP03/04458

**I. Basis of the opinion**

1. The basis of this written opinion is the application as originally filed.

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability**

1. In light of the documents cited in the international search report, it is considered that the invention as defined in at least some of the claims does not appear to meet the criteria mentioned in Article 33(1) PCT, i.e. does not appear to be novel and/or to involve an inventive step (see international search report, in particular the documents cited X and/or Y and corresponding claims references).
2. If amendments are filed, the applicant should comply with the requirements of Rule 66.8 PCT and indicate the basis of the amendments in the documents of the application as originally filed (Article 34 (2) (b) PCT) otherwise these amendments may not be taken into consideration for the establishment of the international preliminary examination report. The attention of the applicant is drawn to the fact that if the application contains an unnecessary plurality of independent claims, no examination of any of the claims will be carried out.

NB: Should the applicant decide to request detailed substantive examination, then an international preliminary examination report will normally be established directly. Exceptionally the examiner may draw up a second written opinion, should this be explicitly requested.